

DETAILED ACTION

Status of the Claims

1. Claims 16-25, 52 and 53 are pending.

Applicants' amendment filed September 23, 2008 is acknowledged. Applicant's response has been fully considered. Claims 16 and 24 have been amended, claims 15 and 26-51 have been cancelled, and new claims 52 and 53 have been added. Therefore, claims 16-25, 52 and 53 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claims 16-51 under 35 U. S. C. 112, first paragraph, new matter, is withdrawn in view of applicants' amendment to the claims, applicants' cancellation of the claims, and applicants' response at page 7 in the amendment filed September 23, 2008.

Withdrawn Claim Rejections -- 35 USC § 102

3. The previous rejection of claims 16-18, 21-23 and 26-51 under 35 U.S.C. 102(a) as being anticipated by Boyko *et al.* (WO 02/03910), is withdrawn in view of applicants' amendment to the claims, applicants' cancellation of the claims, and applicants' response at page 7 in the amendment filed September 23, 2008.

Withdrawn Claim Rejections -- 35 USC § 103

3. The previous rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over Ando *et al.* (U. S. Patent 5,576,299) in view of Ogunbiyi *et al.* (U.S. Patent 4,783,488), is withdrawn in view of applicants' cancellation of the claims, and applicants' response at page 7 in the amendment filed September 23, 2008.

4. The previous rejection of claims 16, 17, 21-23, 26, 28 and 30-47 under 35 U.S.C. 103(a) as being unpatentable over Kruzel *et al.* (US Patent 6,066,469), is withdrawn in view of applicants' amendment to the claims, applicants' cancellation of the claims, and applicants' response at page 8 in the amendment filed September 23, 2008.

Withdrawn Claim Rejections-Obviousness Type Double Patenting

5. The previous rejection of claims 15-51 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent 7,323,443, is withdrawn in view of applicants' amendment to the claims, applicants' cancellation of the claims, and applicants' response at pages 8-9 in the amendment filed September 23, 2008.

6. The previous rejection of claims 16-22, 26-30 and 50-51 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 14, 17-19, 26-32 and 38-40 of copending Application No. 10/728,521, is withdrawn in view of applicants' amendment to the claims, applicants' cancellation of the claims, and applicants' response at page 9 in the amendment filed September 23, 2008.

Examiner's Amendment

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Examiner's Amendments to the Specification:

-Please replace the term "Table 5" in paragraph [0069] at page 15 of the specification with the term "Table A".

The following is an **Examiner's Statement of Reasons for Allowance**: The following references appear to be the closest art to the claimed invention. Boyko *et al.* (WO 02/03910) disclose a preparation of lactoferrin is used for treating wound surface such as third stage cervix uteri cancer and occurrences of recititis, where the preparation can be administered orally, intravenously, intracavitarily or intravesically, in the form of eye drops, inhalations or ointments, and the concentration of the active ingredient is 0.1-0.3% in a solution. Ando *et al.* (U. S. Patent 5,576,299) disclose a formulation containing lactoferrin or transferrin is used for treating opportunistic infectious diseases under immunodeficient condition caused by Lentiviral infection, e.g., granules containing human apolactoferrin (350 mg/day) were given to HIV positive patients with recurrent stomatitis and gingivitis once daily for 4 weeks, and feline immunodeficiency virus (FIV)-positive cats were treated with bovine native lactoferrin. Kruzel *et al.* (US Patent 6,066,469) disclose treating accidental scratches and burns by topical administration of lactoferrin in an ointment, cream or other topical vehicle twice daily in an amount of 50-100 mg per dose for a period of time of three to four weeks. Varadhachary *et al.* (U. S. Patent 7,323,443) disclose a method of treating a subject suffering from pain comprising the step of administering to the subject a lactoferrin composition comprising an N-terminal lactoferrin variant, wherein the pain is associated with recovery from surgery. However, the references do not teach or suggest the use of a lactoferrin composition in treating a patient with diabetic ulcer. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

November 26, 2008